Accuracy and reliability of two indirect ambulatory blood pressure recorders: Remler M2000 and Cardiodyne Sphygmolog

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SUMMARY The Remler M2000 and Cardiodyne Sphygmolog are semiautomatic recorders designed to measure ambulatory blood pressure non-invasively. These recorders were assessed for accuracy and reliability in a study designed in three stages. Firstly, the interdevice variability was assessed separately for each type of recorder by comparing the recordings of three devices against each other and against simultaneous recordings by a mercury standard in 12 patients, multiple recordings being made in a random order in each patient. The mercury standard used was the London School of Hygiene (LSH) sphygmomanometer and the Hawksley random zero sphygmomanometer during assessment of the Remler and Sphygmolog, respectively. Though there were no differences between the three Remler recorders tested, one Sphygmolog recorder gave higher recordings than the two other Sphygmolog recorders tested because of a zero drift of 3 to 4 mmHg in the pressure transducer. Remler recordings were higher than simultaneous LSH sphygmomanometer recordings for both systolic and diastolic pressures. In the second part of the study, the Remler was compared with the Hawksley using simultaneous recordings in the same arm in 58 patients. No difference was found between Hawksley and Remler recordings. The discrepancy between this and the Remler-LSH comparison resulted from a tendency for the LSH sphygmomanometer to underestimate blood pressure. Similarly, the Sphygmolog recordings were compared with simultaneous Hawksley recordings in 100 patients. No significant difference was found between paired systolic pressure recordings though Sphygmolog recordings underestimated diastolic blood pressure. In the third part of the study, the reliability of the Remler was assessed from 69 attempted day recordings. Five Remler day recordings failed, a major cause of lost recordings being a defect in the microphone lead. The reliability of the Sphygmolog was compared with the Remler by attempting day recordings with each device in 13 patients. The reliability of the Sphygmolog was significantly poorer, only five of 13 Sphygmolog day recordings being decodable because of dislodgement of the recording disc during ambulation.

Single clinic recordings may not reflect the blood pressure behaviour of many patients.[1-3] Therefore, methods of assessing blood pressure behaviour outside the clinic have been developed and include home recording by the patient[4 5] or a relative,[6] and intra-arterial[1] and indirect ambulatory recording.[7 8]

Intra-arterial recording is an invasive procedure which is not without risk.[9] Home recording may be inaccurate because of patient bias.[10] Indirect ambulatory blood pressure recording should be free of these disadvantages but there have not been many

studies on the accuracy of the recorders that are now available.

In this paper we present our findings on the accuracy and reliability of two ambulatory blood pressure recorders, the Remler M2000 and Cardiodyne Sphygmolog.

Methods and results

The Remler M2000 is a portable blood pressure recorder consisting of a cuff and microphone connected to a pressure transducer and microcassette
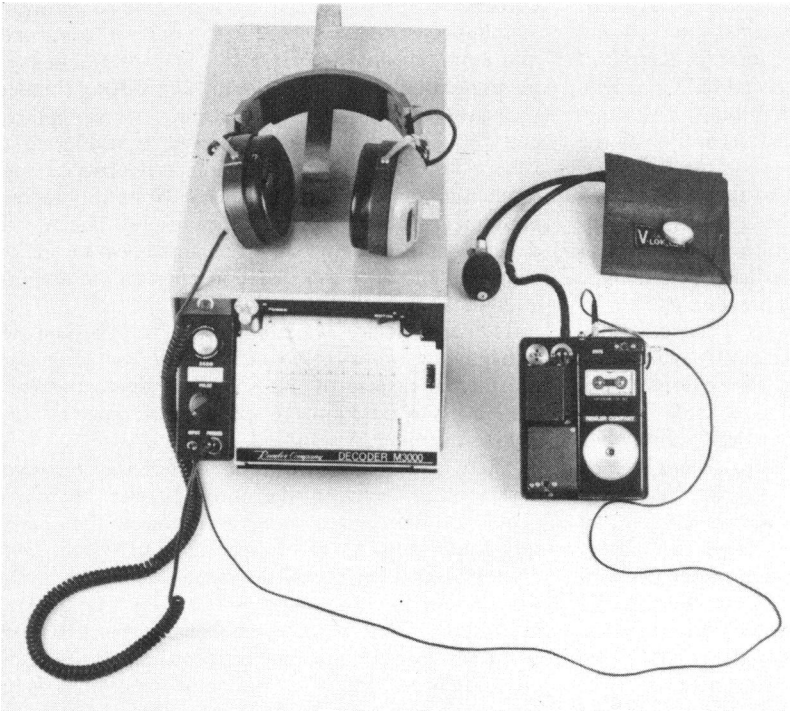
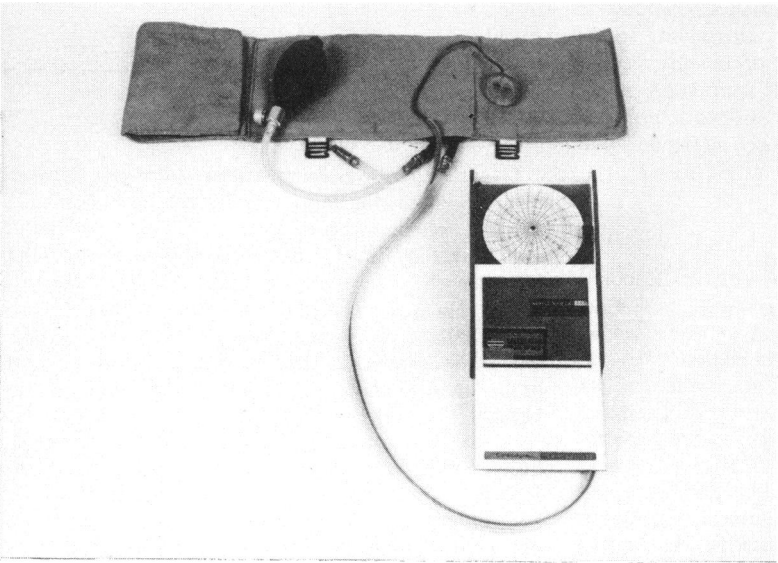Fig. 1 *The Remler M2000 (right) and decoder (left) with example of pressure recording on the strip chart.*

Fig. 2 *The Cardiodyne Sphygmolog.*

recorder worn on the patient's waist (Fig. 1). The cuff is inflated by the patient at prescribed intervals and deflates automatically. During deflation the Korotkoff sounds and cuff pressure are recorded on a magnetic tape. The tape is later analysed through a separate decoder which gives a strip chart recording of the sounds superimposed on a tracing of cuff pressure (Fig. 1). The pressures corresponding to the first and last sounds are recorded as the systolic and diastolic end-points, respectively. As weaker sounds may not deflect the pen in the decoder an observer listens to the tape during decoding and marks on the pressure tracing the position of the first and last sounds. Pen deflections caused by artefacts can be excluded at the same time.

The Cardiodyne Sphygmolog also consists of a sphygmomanometer cuff which is inflated by the patient and which deflates automatically through a needle valve (Fig. 2). The cuff pressure is monitored by a pressure transducer which drives a pen suspended over a paper disc. The Korotkoff sounds are detected by a microphone placed beneath the lower cuff margin and are recorded on to the paper disc by the pen as it moves across the disc. As the disc is calibrated for pressure, the first and last pen marks are recorded as the systolic and diastolic point, respectively. The paper disc is driven by a clockwork mechanism and revolves once in 24 hours. In this way, a real-time recording of daily blood pressures is made. Furthermore, the blood pressure recordings are read directly from the disc, so that a separate decoder or analyser is not required.

For each instrument three devices were tested to detect interdevice variability, a source of possible error in automated devices[11] which may bias the overall assessment of their accuracy. The accuracy of one of each type of recorder was then tested against a mercury standard. As the decision end-points for systolic and diastolic pressures are observer dependent, inter-observer variability in the decoding of pressure recordings was also assessed. The results were analysed by Student's t test for paired data and by linear regression analysis. In all cases phase V was used as the diastolic end-point.

ACCURACY STUDIES
(1) Interdevice variability
The Remler was compared with the London School of Hygiene (LSH) sphygmomanometer[12] in 12 patients as part of an interdevice variability study of three Remler recorders. Paired LSH sphygmomanometer and Remler recordings were made in the same arm by connecting both devices to a single cuff through a Y connector (Fig. 3a). The stethoscope head and microphone were applied to the same brachial artery without difficulty. Simultaneously a second observer recorded paired Remler-LSH sphygmomanometer recordings in the opposite arm by the same technique. As the two

cuffs were interconnected we were able to compare simultaneous Remler recordings in opposite arms and also simultaneous Remler and LSH sphygmomanometer recordings in the same arm. The order of Remler recorders, the arm to which the recorders were applied, and the observers was randomised according to a Graeco-Latin square design. In this way observer and sequential bias, or bias resulting from differences between arms would not influence results. The rate of deflation of the system was set at 3 mmHg per second as we observed that lower deflation rates caused attenuation of the Korotkoff sounds.

The interdevice variability of the Cardiodyne Sphygmolog was assessed in the same way (Fig. 3a) except that instead of the LSH sphygmomanometer the Hawksley random-zero sphygmomanometer[13] was used as the mercury standard.

There was no significant difference between observers or between the three Remler recorders (Table 1). Remler recordings were higher than LSH sphygmomanometer recordings for both systolic and diastolic blood pressures, the mean differences being 4·8 mmHg ($p<0·05$) and 4·7 mmHg ($p<0·005$), respectively. This was true whether the mean Remler and LSH sphygmomanometer recordings for each of the 12 patients (Fig. 4) or individual recordings were compared. Furthermore, the mean differences between paired Remler and LSH sphygmomanometer recordings were negatively correlated with heart rate for diastolic ($r, -0·69$ $n=12$, $p<0·02$) but not systolic blood pressures.

Table 1 *Comparison of three Remler recorders*

	Systolic (mmHg)	Diastolic (mmHg)
Remler 1	161·6±4·5	94·7±1·8
Remler 2	163·4±4·4	93·7±2·1
Remler 3	161 ±4·3	93·4±1·6

Values are mean ± SEM.

Overall, there was no significant difference between paired Sphygmolog and Hawksley recordings in the 12 patients whether the mean data for each patient or individual recordings were compared. One Sphygmolog recorder (S_1), however, significantly overestimated paired Hawksley systolic recordings (Table 2) and comparison of individual paired Sphygmolog recordings in opposite arms showed that S_1 recordings were higher than S_2 and S_3 recordings, the mean difference being 4·3 mmHg ($p<0·01$) for systolic and 2·4 mmHg ($p<0·06$) for diastolic recordings. S_2 and S_3 Sphygmolog recordings tended to underestimate Hawksley diastolic pressure recordings (by 2·8 mmHg on average) while S_1 recordings showed a mean excess of 0·7 mmHg over the Hawksley.

Table 2 *Comparison of paired Hawksley and Sphygmolog recordings for three Sphygmolog recorders*

	Systolic (mmHg)			Diastolic (mmHg)		
	S_1	S_2	S_3	S_1	S_2	S_3
No.	48	48	48	48	48	48
Hawksley	162 ±5·5	161·6±5·3	162±5·4	90 ±1·9	91·3±1·7	91·1±2·0
Sphygmolog	165·6±5·8**	164·8±5·0	161±5·2	90·7±1·8	88·4±1·6*	88·4±1·7*

Values are mean ± SEM. *$p<0.05$, **$p<0.01$ significantly different from paired Hawksley recordings.
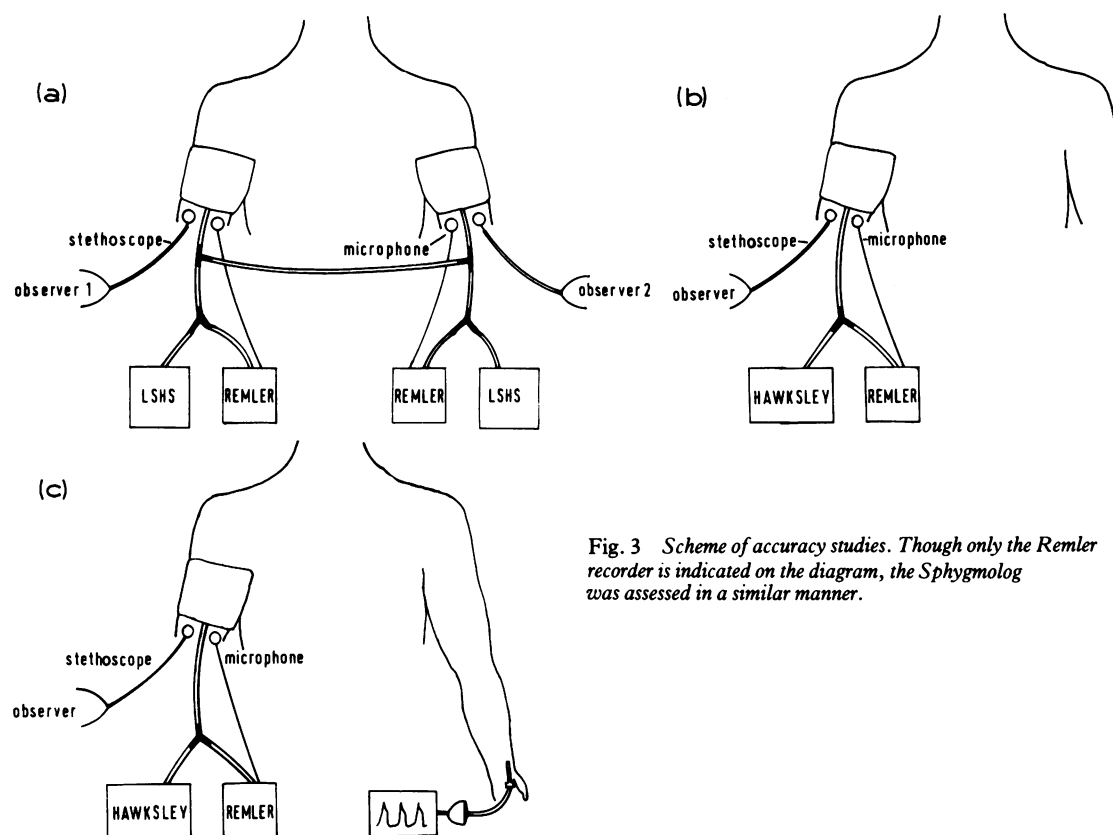

Fig. 3 *Scheme of accuracy studies. Though only the Remler recorder is indicated on the diagram, the Sphygmolog was assessed in a similar manner.*

(2) Comparison of simultaneous Hawksley and automatic device recordings

The Remler was compared with the Hawksley random zero sphygmomanometer in 35 patients using simultaneous recordings in the same arm (Fig. 3b). One Remler recorder and one observer were used. Two recordings were made in each patient as not all Remler recordings would be decodable. There was no significant difference between paired Remler and Hawksley recordings using either the mean data for each patient or individual recordings (Table 3).

Similarly, the Cardiodyne Sphygmolog was com-pared with the Hawksley random zero sphygmomano-meter in 100 patients (Fig. 3b), one recording being made in each patient. There was no significant difference between paired systolic recordings (Table 3). Sphygmolog recordings, however, slightly under-estimated Hawksley diastolic recordings, the mean difference being 2 mmHg.

(3) Comparison of Remler and intra-arterial recordings
In 23 patients, simultaneous Hawksley and Remler recordings were made in the left arm while intra-arterial recordings were recorded from the opposite

Table 3 *Comparison of paired Hawksley and Remler recordings and paired Hawksley and Sphygmolog recordings: Data for Hawksley-Remler recordings represent mean data (± SEM) for each of 35 patients*

	Systolic (mmHg)			Diastolic (mmHg)		
	Hawksley		*Remler*	*Hawksley*		*Remler*
No.	35		35	35		35
Mean ± SEM	162·2±5·0		161·8±5·1	99·5±2·8		99·9±2·8
Correlation coefficient		0·98			0·97	
	Hawksley		*Sphygmolog*	*Hawksley*		*Sphygmolog*
No.	100		100	100		100
Mean ± SEM	160·1±3·0		159·0±2·9	93·8±1·7		92±1·8*
Correlation coefficient		0·98			0·97	

*p<0·001, significantly different from paired Hawksley recordings.
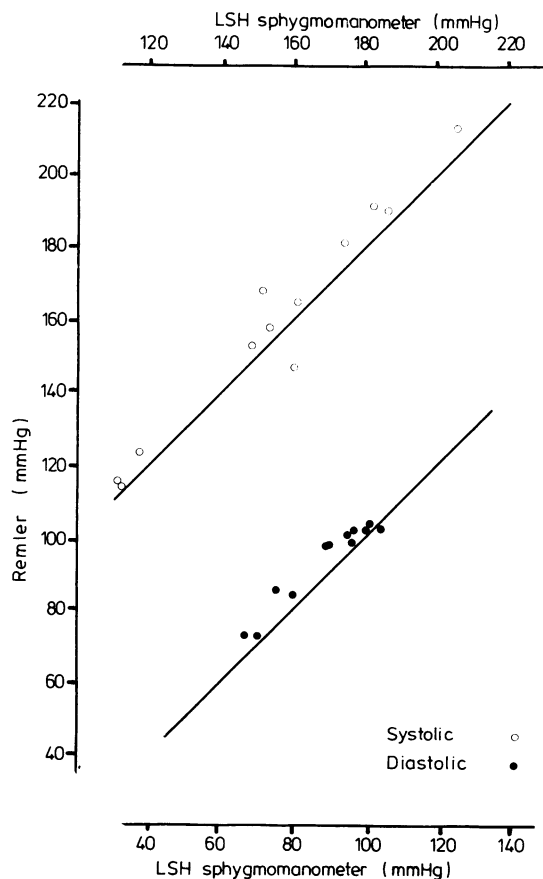

Fig. 4 *Comparison of mean LSH sphygmomanometer and Remler paired recordings in each of 12 patients. Lines of identity are given.*
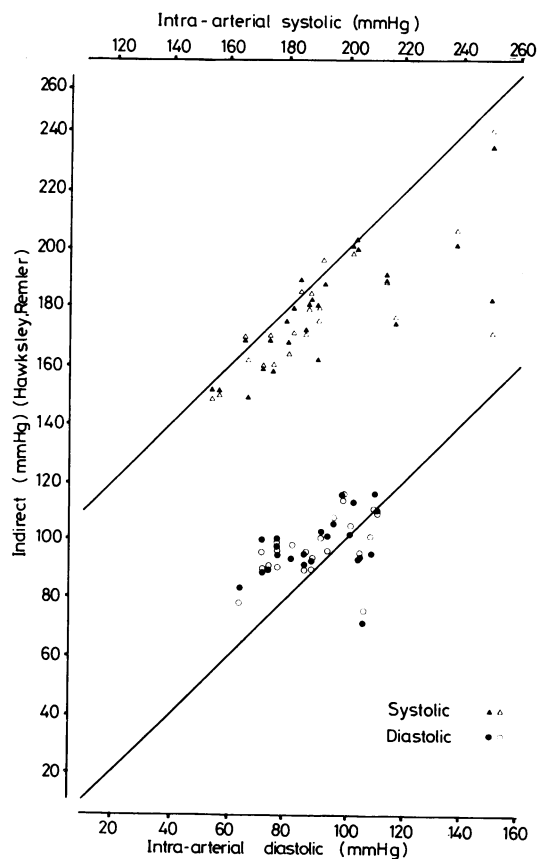

Fig. 5 *Comparison of Remler and Hawksley recordings with intra-atrial recordings. Lines of identity are given. Remler recordings are indicated by the closed symbols and Hawksley recordings by the open symbols.*

radial artery through a Bell and Howell pressure transducer on to light sensitive paper (Fig. 3c). Three recordings were made in each patient as not all Remler recordings would be decodable.

The relation between Remler and intra-arterial recordings was the same as between Hawksley and intra-arterial recordings for both systolic and diastolic blood pressures (Fig. 5, Table 4). Again, there was no significant difference between Hawksley and Remler recordings.

RELIABILITY STUDY

The reliability of the Remler in recording ambulatory blood pressure was assessed by determining the number of decodable recordings from 69 attempted Remler ambulatory day recordings. Of these, five failed completely, in three cases because the microphone lead broke and in two because of a defect in the "off" pressure switch which failed despite normal deflation. In the remaining 64 tapes, 1129 pressure recordings were attempted and 104 (9·2%) of these were undecodable. In 35 (3·1%) this was because of the failure of the microphone to detect any sounds and in the remainder because of either incorrect setting of the on-off pressure switches or patient movement.

In 13 hypertensive patients the reliability of Sphygmolog ambulatory recordings was compared with that of Remler ambulatory recordings. Recordings with each device were carried out in each patient on separate days during normal daily activities. The order of machines was randomised to prevent a training effect and treatment between the two days was not altered.

In only five of 13 Sphygmolog day recordings could a reasonable attempt be made at analyses compared with 12 of 13 Remler day recordings (X^2 5·42 after Yates correction, p<0·02). In the remaining eight, there were no decodable recordings. In six cases this was the due to dislodgement of the paper disc from the motor spindle and in two a large number of artefacts made decoding impossible. The one Remler failure resulted from an excessive cuff deflation rate.

INTEROBSERVER VARIABILITY IN DECODING

Interobserver variability in decoding was assessed by comparing the decoded results of two observers for 120 Remler and 88 Sphygmolog blood pressure recordings made in the laboratory.

There was no significant difference between the two observers in decoding Remler recordings, but 10% of all decoded recordings differed by more than ±5 mmHg, the mean difference being 0·7±4·2 mmHg for systolic and 0·6±5·4 mmHg for diastolic blood pressure recordings. The paired decoded recordings were highly correlated for systolic (r, 0·99, p<0·001) and diastolic (r, 0·93, p<0·001) recordings. Similarly, there was no significant difference between observers for decoding Sphygmolog systolic recordings though there was a small difference for diastolic recordings, the mean being 1 mmHg (p<0·01). The paired decoded recordings were again highly correlated for both systolic (r, 0·98, p<0·001) and diastolic (r, 0·99, p<0·001) pressures. Of the 88 paired decoded recordings, 9·2% of systolic and 5% of diastolic recordings differed by more than 5 mmHg.

Discussion

Accuracy studies of automated blood pressure recorders are beset with problems, including the variation between repeated blood pressure measurements, interdevice variability,[11] observer error,[14] and the type of standards against which they should be tested.[15][16] Where it is possible, as for these two machines, to apply both the standard and automatic recorders to the same brachial artery, comparison of simultaneous recordings in the same arm is the ideal method of assessment.[17] This removes the effect of blood pressure variability, which may otherwise be ascribed to the method of blood pressure recording under test. Furthermore, by comparing the recordings of a number of test instruments made repeatedly in a small group of patients, interdevice differences are easily detected which would otherwise require recordings from large numbers of subjects. Simultaneous mercury sphygmomanometer recordings can be used as a standard against which these differences are confirmed, excluding blood pressure variability as a possible cause.

The accuracy of the Remler M2000 has been assessed previously with varying results.[18-22] In two studies in which the standard used for comparison was the LSH sphygmomanometer, the Remler was found to over-

Table 4   *Comparison of mean Remler, Hawksley, and intra-arterial recordings in each of 23 patients*

	Systolic (mmHg)			Diastolic (mmHg)		
	Remler	Intra-arterial	Hawksley	Remler	Intra-arterial	Hawksley
Mean ± SEM	177·2±4·3	190·6±5·7	178·3±4·4	98·1±2·1	98·5±3·0	97·8±2·0
Mean difference (indirect vs direct)	−13·4**	−12·3**		+8·6**	+8·3**	
Correlation coefficient	0·78***	0·73***		0·4	0·51*	

*p<0·05, **p<0·01, ***p<0·001.

estimate systolic and diastolic blood pressures.[18][20] In contrast, when compared with the Hawksley[22] or a standard mercury sphygmomanometer,[19] the Remler showed no mean bias. In this study the Remler recordings were higher than simultaneous LSH sphygmomanometer recordings, whereas there was no difference between Remler and Hawksley recordings. This is consistent with our previous finding that the LSH sphygmomanometer underestimates blood pressure partly because of incorrect calibration but also because of an interpretative difference between the LSH sphygmomanometer and other methods of blood pressure measurement.[23] The interpretative difference results in an error during blood pressure recording which is heart rate dependent[23] and is confirmed in this study by the negative correlation between the mean Remler-LSH sphygmomanometer differences for diastolic blood pressure and heart rate.

Comparison of Remler and intra-arterial recordings has shown a systematic error of +3/+2 mmHg.[21] The relation of indirect to intra-arterial measurement, however, is highly variable.[24-26] Therefore, comparison of Remler and intra-arterial recordings should be assessed by simultaneous comparison of Remler and mercury sphygmomanometer recordings with intra-arterial recordings. In this study the mean bias and relation between direct and indirect recordings was the same for Remler and Hawksley recordings.

A possible source of variability and bias in Remler recordings is the interobserver difference in the decoding process. Though no significant difference was found between observers, decoded results could differ by more than 5 mmHg in 10% of recordings. This may partly explain the scatter of Remler recordings when compared with standard mercury sphygmomanometer recordings.[23] This interobserver variability, however, is no greater than for standard sphygmomanometer recordings.[15]

The reliability of Remler ambulatory recordings is reduced to a large extent by defects in the microphone lead. This also reduces the availability of the recorder as broken microphones must be returned to the manufacturer for repair, and recorders may lie idle for some time.

The Cardiodyne Sphygmolog is the simplest and most inexpensive complete ambulatory blood pressure system available. Though on the market, it has not been previously evaluated. Accuracy studies showed that the Sphygmolog tended to underestimate diastolic pressure when compared with the Hawksley random-zero sphygmomanometer. This difference, however, was small, and overall this device was reasonably accurate. Interdevice variability studies showed that one recorder gave higher recordings than the two other devices tested. This was the result of a zero drift of 3 to 4 mmHg in the pressure transducer.

Reliability of the Sphygmolog recorder was low. This was not the result of poor technique by the patients as recordings with the Remler M2000 were successful. The main defect, which appears easily correctable, is that the recording discs are displaced from the motor spindle when the machine is in the upright position during ambulatory recording. Even if this were corrected, however, there were a large number of artefacts in two of the remaining day recordings. This may be because of oversensitivity of the recording system, which would explain the tendency to underestimate diastolic pressure, and the absence of any system in the recorder for artefact suppression. Artefactual recording is a major problem during automated blood pressure recording,[27] the commonest cause being movement of the patient's arm. This may be overcome by either using appropriate band filters,[28][29] so that only sounds with the frequency characteristics of Korotkoff sounds[30] are recorded, or by recording sounds occurring within a short period after the QRS complex of the electrocardiogram.[8][31-33] With some systems[7][34] the observer analyses the recorded data and artefacts are rejected on the basis of the occurrence of sounds in an expected position or sequence, or by rejecting recordings altogether as undecodable. In contrast, the permanent record of the pressure measurements made by the Sphygmolog gives no indication whether pen marks are the result of Korotkoff sounds, arm movement, or extraneous sounds.

In conclusion, the Remler M2000 semiautomatic portable recorder is accurate in the measurement of blood pressure. Differences in the findings of previous studies can be explained by the different standards used for comparison. The reliability of the Remler M2000 could be improved by strengthening the microphone lead attachment to the microcassette recorder. The Sphygmolog is a reasonably accurate though unreliable method of recording ambulatory blood pressure. Reliability is poor mainly because of a defect in the method used to retain the paper discs on the revolving spindle of the motor. The Cardiodyne Sphygmolog, as presently designed, cannot be recommended for ambulatory blood pressure monitoring.

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